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What Do You Mean When You Say Quality System?

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What Do You Mean When You Say Quality System?

cGMP's for the 21st Century Initiative

FDA Quality System Framework

Definitions

- Quality Control
- Quality Assurance
- Quality Management
- Quality System



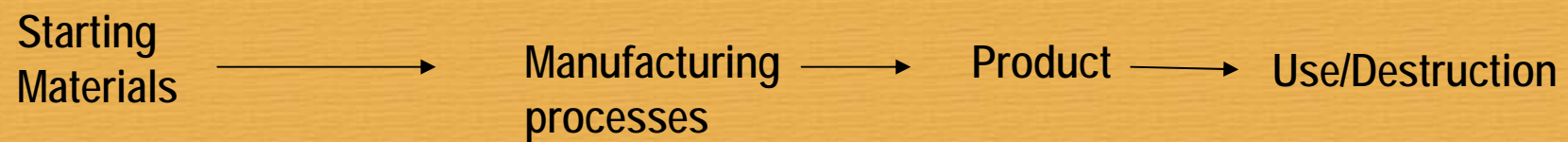
CBER QS Activities

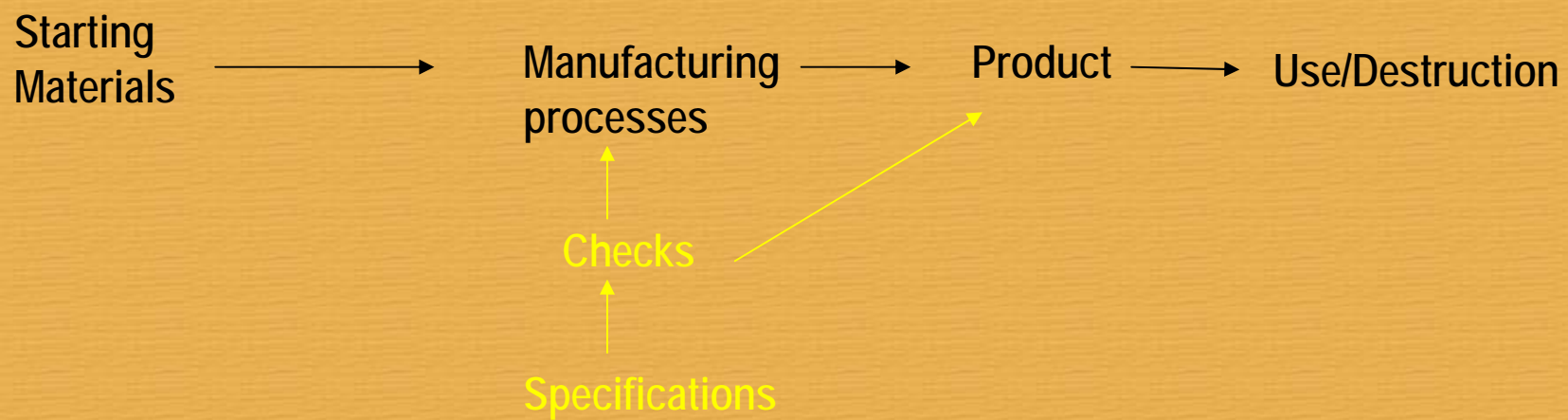
- Lab Quality System
- Managed Review Process
- IT CMMI

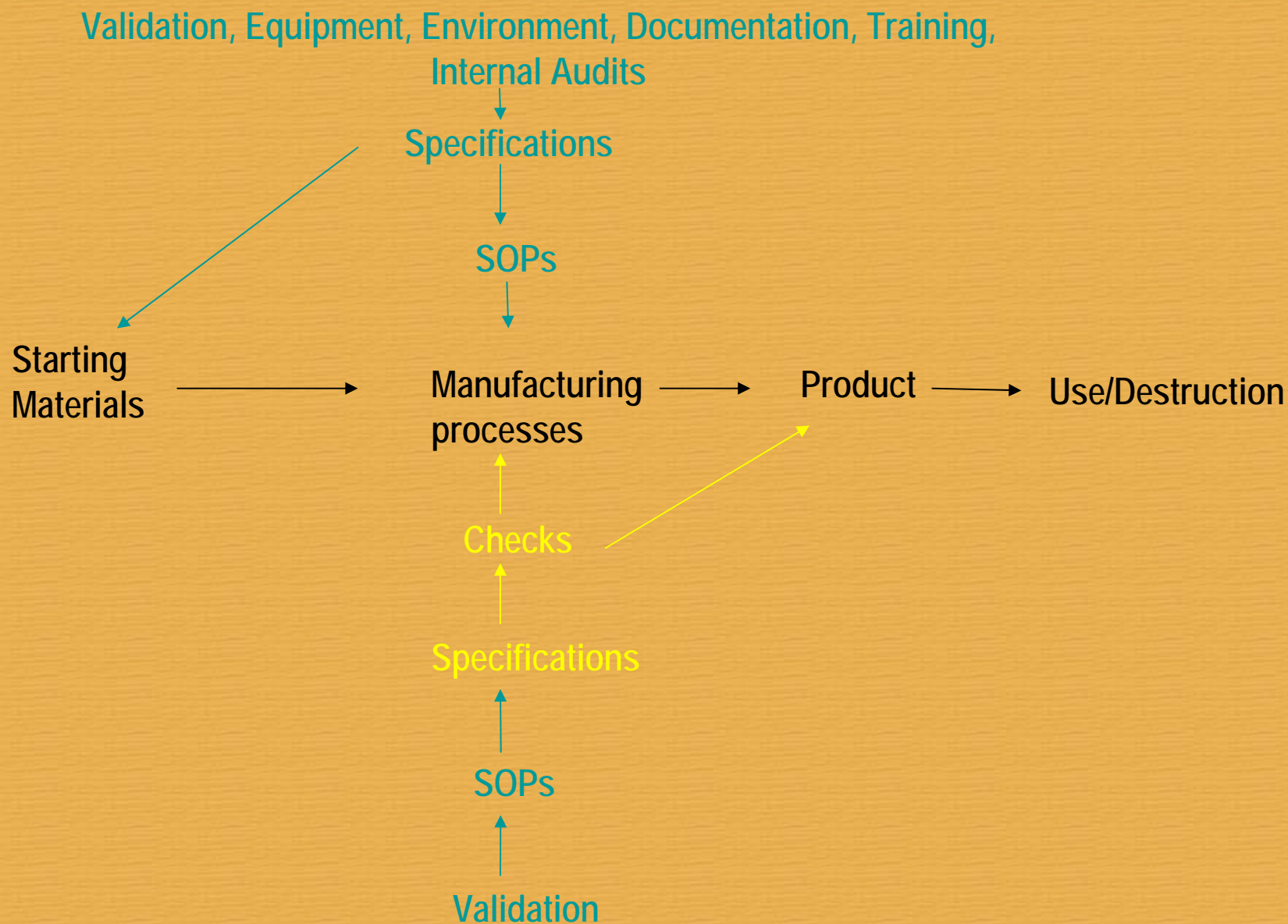


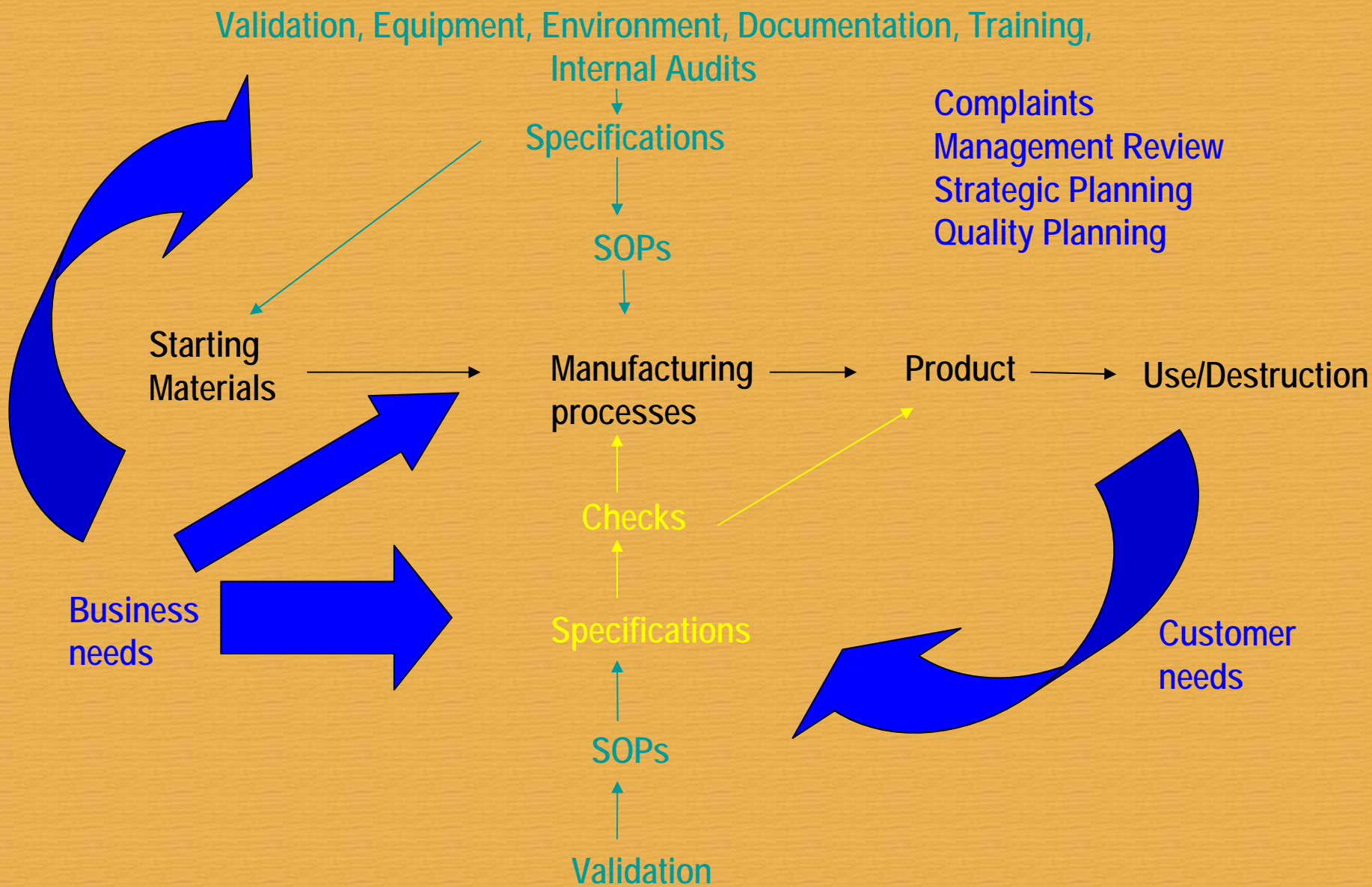
So, what do we mean when
we're talking about 'quality'?











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Definitions - 1

- **Product/Service** - the intended results of activities or processes; products/services can be tangible or intangible.
- **Customer** - a person or organization (internal or external) that receives a product or service anywhere along the product's life-cycle.
- **Stakeholders** - an individual or organization having an ownership or interest in the delivery, results and metrics of the quality system framework or business process improvements.
- **Quality** - a measure of a product's or service's ability to satisfy the customer's stated or implied needs.
- **Quality Policy** - a statement of intentions and direction issued by the highest level of the organization related to satisfying customers' needs. It is similar to a strategic direction that communicates quality expectations that the organization is striving to achieve.
- **Quality Planning** - a management activity that sets quality objectives and defines the operational and/or quality system processes and the resources needed to fulfill the objectives.
- **Quality Objectives** - specific measurable activities or processes to meet the intentions and directions as defined in the quality policy.



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Definitions - 2

- **Quality System** - formalized business practices that define management responsibilities for organizational structure, processes, procedures and resources needed to fulfill product/service requirements, customer satisfaction, and continual improvement.
- **Quality Management** - accountability for the successful implementation of the quality system.
- **Quality Plan** - the documented result of quality planning that is disseminated to all relevant levels of the organization.
- **Quality Control** - the steps taken during the generation of a product or service to ensure that it meets requirements and that the product or service is reproducible.
- **Quality Assurance** - proactive and retrospective activities that provide confidence that requirements are fulfilled.
- **Continuous Improvement** - ongoing activities to evaluate and positively change products, processes, and the quality system to increase effectiveness.



CBER's Quality System Efforts



CBER QS Activities

- Lab Quality System
- Managed Review Process
- IT CMMI



CBER Lab Quality Systems - 1

- Agency Mandate
 - In 1999, the FDA Leadership Council and the Commissioner endorsed a proposal from the Senior Science Council that each FDA Center and the Office of Regulatory Affairs (ORA) independently pursue accreditation of official testing activities according to individual center needs and activities.
- Defined “Official” testing
 - CBER functionally defined ‘official testing’ as lab testing that has a direct impact on a regulatory position taken by the Center, i.e. licensure of new products, routine release of product into the marketplace, approval of changes to licensed products, compliance action, or formal international collaboration.
- Selected Standard ISO 17025
 - “General requirements for the competence of testing and calibration laboratories”



CBER Lab Quality Systems - 2

- Conducted in-depth review and evaluation of the Lot Release activities at CBER
- Developed and issued a Center Lab Quality Policy Manual
- Issued/Drafted
 - Center-level Procedures
 - Office/Division/Lab-specific Work Instructions
- Serving as a technical resource for investigational sample investigations
- Implemented a sample tracking program
- Implementing quality system software tool
- Working to share information between several Center and Agency databases to facilitate lab work-flow



CBER Lab Quality Systems - 3

- Designing/establishing
 - Internal auditing program
 - Lab quality system training program
 - Supplier/reagent qualification program
 - Equipment maintenance and calibration program
 - Validation/qualification program
- Strengthening the physical standards development program
- Participating in lab design for White Oak facilities



Agency Lab Quality Systems

- ORA - ISO17025
 - At least 8 labs accredited, 5 pending
- CDRH – ISO 17025
 - Mammography equipment calibration lab accredited
- CDER - ISO17025
 - Working with CBER to build parallel systems
- CVM - GLP
- CFSAN - GLP
- NCTR - No 'official' testing



Questions or comments

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